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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,915	11/13/2001	Christine Nicol	2296.2320	7698

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FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/21/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/806,915

Applicant(s)

NICOL ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7-18,20-25,28-30 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7-18,20-25,28-30 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, amendment, remarks and declaration, all filed 10/11/06. Claims 1, 2, 7-18, 20-25, 28-30 and 34 are pending.

Claim Rejections - 35 USC § 103

1. Claims 1, 2, 7-18, 22, 23, 28-30 and 34 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Winskill et al. (In Applied Animal Behavior Science, 1996, Vol. 48, pp 25-35) in view of Johnson et al. (In Equine Veterinary Journal, 1998, MARCH, Vol. 30 (2) 139-143) further in view of Pagan (In Australian Equine Veterinarian, Vol. 16 (4) Summer 1998); all previously provided. The amendment of the claims to recite oral administration puts claims 20 and 21 in play and are thus included in the rejection because, since it is known in the prior art that carbonate antacid reduces stereotypy, it would be obvious to one of ordinary skill in the art at the time the invention was made to include the carbonate or Founderguard in the animals feed from birth or in the diet of lactating mother and expect that the baby animal fed the fortified food would grow up to an animal with a reduced tendency of stereotypy

Winskill discloses feeding horse with food composition in pelleted form and the food comprises 100 g protein, 200 g fiber, 27.5 g oil and 85 g ash in addition to feeding the horse on concentrates and "timothy hay" (pages 27 and 28). The horses in Winskill exhibited stereotypic behavior and in the abstract in Winskill it is suggested that stereotypy may be caused by the horse's inability to express foraging behavior (lines 1 and 2 of the abstract). In Winskill's study, the horses expressed foraging behavior when fed the feed comprising fiber and oil (fat). Winskill teaches the composition of the instant claims except that Winskill does not teach a feed composition that contains an antacid.

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Johnson discloses that sodium carbonate, an antacid, can be administered to stabled horses to neutralize acidity of hindgut and neutralizing the acidity lowers the incidence of stereotypic behavior (page 39, right column, first paragraph). Johnson recruits 4-10 year old male and female horses in the study where the horses were fed hay and concentrate in alternate week and one of the groups has the feed supplemented with Founderguard (page 140, left column, lines 10-20). The feed also contained crude fiber and crude protein (page 140, left column, lines 21-28). The horses were observed for grasping, wood chewing, cribbing and wind sucking (left column of page 140, lines 42 to the end). Cribbing and wind sucking are stereotypic behaviors. The result of the study is that Founderguard led to a reduction in abnormal behavior or stereotypic behavior by reducing acidosis of the hindgut. Since the horses were purchased and placed in the study, the horses have to have been weaned although the art is silent on that and examiners position is that the horses in Johnson's study encompasses the scope of recently weaned or weaning as recited in claim 14 or being weaned as recited in claim 22 or following weaning as recited in claim 23 or weaned as recited in claim 15. Regarding claim 13, examiner takes the position that the stomach pH of the horse is controlled before or shortly after the horse develops stereotypic behavior since the result in Johnson states that administration of Founderguard reduces abnormal behavior by controlling hindgut acidosis. Regarding claim 12, examiner's position is that Johnson's study treated the horses before the stereotypic behavior is permanent or "fixed" as recited in said claim; the examiners position is supported by applicant's admitted prior art on page 7, lines 10-17 that an animal should be treated once the stereotypic behavior is observed before the stereotypy is fixed or permanent since the animal will continue to perform the stereotypic behavior once the behavior is fixed.

Johnson suggests a relationship between pH or acidity of the hindgut and behavioral responses (first and second paragraph, right column, last 2 lines, page 139) and specifically states that neutralizing acidity of the hindgut by administering sodium carbonate lowers the incidence of stereotypic behavior (last four lines of first paragraph, right column, page 139). A combined teaching of Winskill and Johnson is a method of feeding horses with a feed that comprises fat, fiber, protein, hay and where Founderguard supplements the feed for treating stereotypic behavior in animals. Johnson and Winskill clearly teach the method of the instant claims except that the combined teaching of Johnson and Winskill does not teach administering proton pump inhibitor or histamine type-2 antagonist to control stomach pH, although Johnson suggests that neutralizing acidity of the hindgut with sodium carbonate lowers the incidence of stereotypic behavior.

But, Pagan teaches treating equine ulcers by neutralizing acidity with histamine type-2 antagonists (cimetidine and ranitidine) or proton pump inhibitors such as omeprazole or prostaglandin analogues or equine antacid such as the patented antacid Neigh-Lox (pages 160 and 161). Instant claim 11 is interpreted as a method of treatment or amelioration of stereotypy, the method comprising administering a composition that contains antacid to control stomach pH of an animal for examination purposes. The method is administration.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the composition of Winskill to treat stereotypic behavior and to incorporate antacid of Johnson or Pagan with the expectation of lowering or reducing the acidity of the hindgut. One having ordinary skill in the art would have been motivated to do this in order to lower the incidence of stereotypic behavior and with the expectation that the histamine type-2

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antagonists or proton pump inhibitor will reduce or inhibit gastric secretion leading to treatment of stereotypy or cribbing.

2. Claims 24 and 25 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (In Equine Veterinary Journal, 1998, MARCH, Vol. 30 (2) 139-143) and Winskill et al. (In Applied Animal Behavior Science, 1966, Vo. 48, pp 25-35) in view of Pagan (In Australian Equine Veterinarian, Vol. 16 (4) Summer 1998).

Winskill discloses feeding horse with food composition in pelleted form and the food comprises 100 g protein, 200 g fiber, 27.5 g oil and 85 g ash in addition to feeding the horse on concentrates and “timothy hay” (pages 27 and 28). The horses in Winskill exhibited stereotypic behavior and in the abstract in Winskill it is suggested that stereotypy may be caused by the horse’s inability to express foraging behavior (lines 1 and 2 of the abstract). In Winskill’s study, the horses expressed foraging behavior when fed the feed comprising fiber and oil (fat).

Johnson suggests a relationship between pH or acidity of the hindgut and behavioral responses (first and second paragraph, right column, last 2 lines, page 139) and specifically states that neutralizing acidity of the hindgut by administering sodium carbonate lowers the incidence of stereotypic behavior (last four lines of first paragraph, right column, page 139).

But, Pagan teaches treating equine ulcers by neutralizing acidity with histamine type-2 antagonists (cimetidine and ranitidine) or proton pump inhibitors such as omeprazole or prostaglandin analogues or equine antacid such as the patented antacid Neigh-Lox and the above three classes of drugs inhibit gastric secretion (pages 160 and 161).

A combined teaching of Winskill and Johnson is a method of feeding horses with a feed that comprises fat, fiber, protein, hay and where the feed is supplemented by Founderguard for treating stereotypic behavior in animals and the Founderguard controls hindgut acidosis.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combined teaching of Winskill, Pagan and Johnson. One having ordinary skill in the art would have been motivated to include the antacid of Johnson or Pagan in the feed of Winskill as feed for horses and the modified composition would be expected to reduce hindgut acidity or control the pH of the hindgut and thus minimize the incidence of stereotypy in horses.

Response to Arguments

3. Applicant's arguments filed 10/11/06 have been fully considered but they are not persuasive.

Applicant argues that a) an oral feed does not support combining the feed of Winskill with the sodium carbonate of Johnson, because any combination of sodium carbonate with the feed of Winskill would “result in the prior art being modified unsatisfactorily for its intended purpose.” b) that Pagan fails to recognize the link between stomach pH and stereotypy.

Response:

a) Johnson feeds horses with hay and teaches that administration of sodium carbonate, known antacid, to stabled horses lowers acidity of hindgut and the lowering of the acidity lowers stereotypic behavior. And Johnson orally feed the horses with hay and therefore, administration of the antacid sodium carbonate is by way of oral feed. Since the carbonate in

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Johnson produces the desired effect when orally administered, then addition of the carbonate to the feed of Winskill would also produce the desired effect and examiner does not see the inconsistency applicant refers. Furthermore, Johnson's feed contains Founderguard and Johnson observes that both the carbonate and the Founderguard lead to the reduction in stereotypic behavior. Thus combination of carbonate or the Founderguard containing feed with the feed (hay) of Winskill would provide the benefits of the carbonate and the Founderguard. Oral administration is contemplated in both prior art references. Therefore, contrary to applicant's contention, one having ordinary skill in the art knowing the benefits of carbonate and Founderguard would expect that addition of these agents, carbonate and Founderguard would produce reduction in stereotypic behavior which is the desired effect from the disclosure of Johnson. The amended claims 11 and 34 recite that effect disclosed in the prior art and these claims are rendered obvious according to the rejection.

b) Johnson recognizes the relationship of acidity and stereotypy and specifically notes that lowering of acidity leads to reduction in stereotypy. Thus, it flows that reduction in the acidity of the intestinal tract would lead to reduction in stereotypy. Therefore, Pagan's teaching is a further support for incorporating the histamine type 2 antagonists to reduce acidity and thus reduction in stereotypy.

Applicant addresses the individual references and does not consider the combined references. NA by so doing, applicant argues the references individually and one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The declaration:

The declaration centers on applicants contention that because hindgut differs from the stomach, carbonate cannot be included in the feed of Winskill.

However, the stomach, the ceacum and the hindgut are all part of the equine digestive system. Although, applicant contends that because the different parts of the equine digestive system have different pH environment, oral administration of the carbonate would produce the anticipated effect. Furthermore, at least claims 1, 2, 7-10 are composition claims and the intended use of the composition would not patentably distinguish the claimed composition over the composition of the prior art. The method administers the composition which the prior art has identified as having positive effect in the reduction of stereotypy. Applicant appears to be casting doubt on the disclosure of the prior art teaching that Founderguard and carbonate and histamine type-2 antagonist reduce acidity and stereotypy. But, the prior art is what the prior art is.

Therefore, the rejections are maintained.

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action, the inclusion of claims 20 and 21 with the rejection in light of the amendment of the claims to reflect oral administration. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Arguments

Applicants state that neither Johnson, Winskill nor Pagan identifies the relationship between stereotypic behavior in animals and stomach acidity and that any combination thereof would likely fail to operate according to the teaching of the instant claims.

Response to Arguments

5. Applicants' arguments filed 04/25/05 have been fully considered but they are not persuasive.

Johnson is relied upon for a disclosure of feed/food containing antacid that lowers incidence of stereotypy in horses. The goal of Winskill is to reduce stereotypy or increase foraging in horses and Winskill's feed composition though containing no antacid was effective in combination with football to increase foraging time and thus lowered stereotypy. Thus a third composition can be formulated from the combination of Winskill and Johnson as a feed for horses and the motivation of including the antacid of Johnson is produce a feed that would be expected to lower the incidence of stereotypy. Thus, without considering the future intended use of claim 1, the combination of Winskill and Johnson produces a food composition that is

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within the scope of instant claim 1. Also, the combined teaching of Winskill and Johnson is within the scope of the claim 1 even when the future intended use is called into play.

Same compositions would have same characteristics. Winskill talks about reducing stereotypy or increase foraging. The method claim 11 administers stomach antacid to an animal and the administration of the antacid does not exclude oral administration. Sodium bicarbonate is also a stomach antacid (abstract of JP 02069421 as a teaching reference). As discussed above, there is an expectation of success that stereotypy in the horses will be lowered when an antacid is included in the composition of Winskill. Johnson discloses controlling acidity in horses/equine. Pagan discloses neutralizing acidity in equine with histamine type-2 antagonists and equine antacid. Since bicarbonate and histamine type-2 antagonists and equine antacid control acidity in the horse/equine, it is prima facie obvious to substitute one antacid for the other and expect to produce the same effect of acidity control. Therefore, a combination of Pagan with Winskill and Johnson is proper and would necessarily have the characteristic of the composition. It is further noted that the claim 1 is a product or composition claim and the intended use of the composition carries no patentable weight.

It is noted that Winskill discloses the relationship of foraging and stereotypy and feed composition of fat (oil) and fiber combined with football activity. However, the instant claim 1 is a composition that comprises antacid, fiber and oil; and instant claim 11 administers antacid to lower or minimize or ameliorate or treat animal stereotypy. The claims do not state that stereotypy is lowered or minimized or ameliorated by administering fiber and oil composition and thus the argument that Winskill does not recognize that fiber and oil composition is effective in treating stereotypy is not within the scope of the examined claims. Thus the references taken

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together disclose the composition of the instant claims and discloses also the method of the instant claims. Therefore, the combination is proper. Acidity is related to pH and controlling the pH is also controlling acidity or pH.

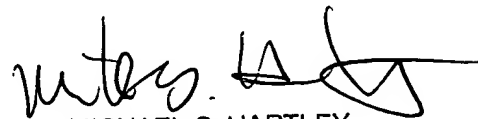
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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